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Original Article

Management of Birth Asphyxia in Home Deliveries in Rural Gadchiroli: The Effect of Two Types of Birth Attendants and of Resuscitating with Mouth-to-Mouth, Tube-Mask or Bag–Mask

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OBJECTIVES:

To evaluate the effect of home-based neonatal care on birth asphyxia and to compare the effectiveness of two types of workers and three methods of resuscitation in home delivery.

STUDY DESIGN:

In a field trial of home-based neonatal care in rural Gadchiroli, India, birth asphyxia in home deliveries was managed differently during different phases. Trained traditional birth attendants (TBA) used mouth-to-mouth resuscitation in the baseline years (1993 to 1995). Additional village health workers (VHWs) only observed in 1995 to 1996. In the intervention years (1996 to 2003), they used tube-mask (1996 to 1999) and bag-mask (1999 to 2003). The incidence, case fatality (CF) and asphyxia-specific mortality rate (ASMR) during different phases were compared.

RESULTS:

During the intervention years, 5033 home deliveries occurred. VHWs were present during 84% home deliveries. The incidence of mild birth asphyxia decreased by 60%, from 14% in the observation year (1995 to 1996) to 6% in the intervention years ($p<0.0001$). The incidence of severe asphyxia did not change significantly, but the CF in neonates with severe asphyxia decreased by 47.5%, from 39 to 20% ($p<0.07$) and ASMR by 65%, from 11 to 4% ($p<0.02$). Mouth-to-mouth resuscitation reduced the ASMR by 12%, tube–mask further reduced the CF by 27% and the ASMR by 67%. The bag–mask showed an additional decrease in CF of 39% and in the fresh stillbirth rate of 33% in comparison to tube–mask (not significant). The cost of bag and mask was $13 per averted death. Oxytocic injection administered by unqualified doctors showed an odds ratio of three for the occurrence of severe asphyxia or fresh stillbirth.

CONCLUSIONS:

Home-based interventions delivered by a team of TBA and a semiskilled VHW reduced the asphyxia-related neonatal mortality by 65% compared to only TBA. The bag–mask appears to be superior to tube–mask or mouth-to-mouth resuscitation, with an estimated equipment cost of $13 per death averted.

Journal of Perinatology (2005) **25,** S82–S91. doi:10.1038/sj.jp.7211275

INTRODUCTION

The World Health Organization (WHO) estimates that globally, between four and nine million newborns suffer birth asphyxia each year. Of those, an estimated 1.2 million die and almost the same number develop severe consequences.[1] The WHO also estimates that globally, 29% of neonatal deaths are caused by birth asphyxia.[2] In addition, a sizable proportion of stillbirths are caused by asphyxia. Wiggleworth's classification of perinatal deaths equates fresh stillbirths with birth asphyxia,[3] and this was validated by a prospective study in the UK.[4] Thus, birth asphyxia or perinatal asphyxia is a huge global problem with fresh stillbirth, neonatal death and long-term neurodevelopmental problems as its main serious outcomes.

Ellis and Manandhar, based on a literature search of published studies from 20 developing countries in the previous 15 years, estimate that 24 to 61% of perinatal mortality was attributable to asphyxia. The cause-specific perinatal mortality rate associated with asphyxia was generally between 10 and 20 per 1000 births.[5]

Perinatal asphyxia can result from inadequate supply of oxygen immediately before, during or just after delivery. Apart from fetal hypoxia, conditions such as prematurity or congenital anomaly can also result in a failure to establish adequate breathing at birth and manifest as ''asphyxia''. In the field setting in developing countries intrapartum monitoring or the finer clinical observations at birth, such as heart sounds, heart rate or presence of umbilical arterial pulsation, are not available on home-delivered neonates. In

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The Financial Support for this work came from The John D. and Catherine T. MacArthur Foundation, The Ford Foundation, Saving Newborn Lives, Save the Children, USA and The Bill & Melinda Gates Foundation.

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such situation, it is impossible to classify or diagnose the cause in a neonate depressed at birth. One practical solution to this problem is to use the term ''birth asphyxia'' for the clinical condition of failure to initiate or maintain regular breathing at birth and hence requiring resuscitation. This does not relate to the cause. The outcome can be (i) a freshstill birth, or a severely asphyxiated neonate who is not resuscitated and hence counted as ''fresh stillbirth'', (ii) an asphyxiated live neonate who can subsequently die during neonatal period (asphyxia-related mortality), (iii) survive with neurological disability or (iv) survive as a normal infant.

The estimated incidence of the problem depends upon how it is defined and measured. The Apgar score is the common method used in hospitals. For the community setting, the National Neonatology Forum of India has suggested, ''gasping and ineffective breathing or lack of breathing at one minute after birth''[6] and it has been equated with an Apgar score of three or less.[7] Almost all available estimates of asphyxia in home-delivered neonates used retrospective inquiry to the family about the description of the events at birth.[8,9] The validity of such estimates is doubtful.

In what is probably the first ever prospectively observed epidemiologic study of home deliveries and neonates in the community, we found the incidence of mild birth asphyxia to be 14.2% and of severe asphyxia to be 4.6% in the observational year, 1995 to 1996 in the field trial of the home-based neonatal care in Gadchiroli, India.[10,11] Mild and severe asphyxia were mutually exclusive categories. Mild asphyxia was defined as no cry, or breathing absent or slow, weak or gasping, at 1 minute after birth. Severe asphyxia was defined as breathing absent or slow, weak or gasping at 5 minutes after birth. (See Table 1 for the incidence and the mortality associated with asphyxia in this year.) The case fatality (CF) in mild asphyxia was low, and it was not associated with the risk of mortality (relative risk (RR), 0.5) but severe asphyxia had an RR of 8.0. The primary cause of death was assigned by an independent neonatologist. The asphyxia-specific mortality rate (ASMR) was 10.5/1000 live births when the NMR was 52/1000 live births in 1995 to 1996.[12]

We have also estimated the population attributable risk of asphyxia in Gadchiroli in 1995 to 1996 to be 0.35, next only to preterm birth (0.74), intrauterine growth restriction (0.55) and sepsis (0.55).[13]

The field trial of home-based neonatal care in Gadchiroli included management of birth asphyxia as a part of the package of home-based interventions. The interventions were introduced against a background of the morbidity and mortality described above and were continued from 1996 through 2003. The objectives of this article are:

1. To evaluate the effect of the home-based management of birth asphyxia. We selected the following indicators for evaluation:
   (i) Proportion of home deliveries in which the trained village health worker (VHW) was present.
   (ii) Incidence of birth asphyxia — mild and severe;
   (iii) CF in severe asphyxia;
   (iv) ASMR;
   (v) fresh stillbirth rate (SBR).
2. To compare the effectiveness of the two sets of birth attendants, only traditional birth attendant (TBA) and the TBA plus VHW, and the three methods of resuscitation used in the field trial, namely, mouth-to-mouth breathing by the TBAs, tube and mask used by trained VHWs, and bag and mask used by trained VHWs.

The comparisons were made before–after (1995 to 1996 vs 1996 to 2003) for the most part. For a few outcomes, it was with the concurrent control area.

MATERIALS AND METHODS

The area, available health care, study design, and data collection methods in the field trial of home-based neonatal care have been earlier described.[10,14–16] Here we describe only the salient points in relation to the measurement of indicators and the management of birth asphyxia.

Data collection

SEARCH (Society for Education, Action and Research in Community Health) had selected an intervention and a control

Table 1 Birth Asphyxia in 1995–1996: The Baseline

	Incidence		Case fatality		RR	Mortality rate
	Cases/neonates	%	Deaths/cases	%		
Mild asphyxia*	81/570	14.2	3/81	3.7	0.5	—
Severe asphyxia†	26/570	4.6	10/26	38.5	8.0	—
Asphyxia specific mortality rate/1000 live births	—	—	—	—	—	10.5

*At 1 minute after birth, no cry, or the breath was absent or slow, weak or gasping.
†At 5 minutes after birth, the breath was absent or slow, weak or gasping.
RR = relative risk of death.

area in the Gadchiroli district, India, in 1988, and established a vital statistics surveillance system by using male VHWs and male field supervisors.[15,17] Trained field supervisors conducted ''verbal autopsy'' by visiting families where there had been the death of a child or a stillbirth. The criteria for diagnosing cause of death by verbal autopsy and the results of the cause of death have been published.[17,18] This verbal autopsy was continued until 1999, when it was stopped. Because nearly 95% births occurred at home, attended by TBAs, we had trained the TBAs in the intervention villages in 1988 in safe and hygienic home delivery, and in mouth-to-mouth resuscitation of babies who failed to cry or breathe at birth.[17,19]

The field trial of home-based neonatal care was conducted in this area from 1993 to 1998. During 1993 to 1995 only the baseline vital statistics were collected in 39 intervention and 47 control villages in which TBAs conducted most of the deliveries. In 1995 to 1996, female VHWs were trained in the intervention area. They attended home deliveries conducted by the TBAs in their villages and observed newborns at 1 and at 5 minutes after birth, and by making eight subsequent home visits.[11,14] They recorded the data about pregnancy, delivery and newborn on a mother–newborn printed record that was checked in the field by a visiting physician.

To determine the causes of deaths in children, the verbal autopsy was continued in the intervention and the control areas from 1988 to 1999. The ASMR was estimated from these data. In addition, from 1995, the prospectively observed mother–newborn records of the neonatal deaths in the intervention area were reviewed by an independent neonatologist (VK Paul, Department of Pediatrics, All India Institute of Medical Sciences, New Delhi) who assigned the most probable primary cause of death.[12] The ASMR was estimated from these data. The method used to estimate the ASMR (verbal autopsy or neonatologist) was specified.

The data from the records of neonates observed by the female VHWs were computerized. Using the definitions described in the Introduction section, a computer algorithm diagnosed mild and severe birth asphyxia.[10,11]

Stillbirths were recorded by the vital statistics surveillance system as well as by the female VHWs who attended home deliveries and were verified by supervisors by visiting the family. Stillbirth was defined as a birth (completed 28 weeks gestation) in which the fetus did not breathe or cry or show movement of chest or limbs at birth. The weight of the stillborn fetus was not measured. The VHWs observed and recorded the stillborn fetus as ''fresh'' or ''macerated'' from 1996 onwards. Using our definition, a ''fresh stillbirth'' could include an intrapartum fetal death or a severely asphyxiated neonate who did not cry or breathe, and who could not be resuscitated, and hence was considered as a fresh stillbirth. Due to this definition, the intervention of resucitation at birth could theoretically reduce the fresh SBR.

Using these data in the intervention area, the incidence of birth asphyxia (mild or severe), ASMR based on the birth asphyxia as the primary cause of death, and fresh SBR were estimated only in the intervention villages. These three estimates were not possible in the control area in the absence of prospectively observed data. The fresh SBR was estimated from 1996 to 2003.

Interventions

Different interventions during different periods and the available indicators are shown in Figure 1. Most home deliveries were attended by the TBAs. The VHWs were resident women of the village, with 5 to 10 years of schooling. After initial training and 1 year of observing home deliveries and neonates without intervention (1995 to 1996) they were trained in how to manage a baby at birth and how to manage those who did not cry or breathe at birth by following an algorithm (see Box 1). The training was given in a 3-day workshop, followed by review, practice and assessment in the next workshop 2 months later. Since the occasion to deal with an asphyxiated baby and the need for resuscitation occur only infrequently, their skills were kept up by way of drills practiced on dummy dolls every 2 months. From 1996, the VHWs took charge of newborns from the TBAs. The VHW cleaned immediately the mouth of the newborn and dried the skin with a clean cloth, diagnosed birth asphyxia and managed as shown in Box 1.

Box 1 Diagnosis and Management of Asphyxia by VHW

1. Be present at the time of birth.
2. Be prepared to face an asphyxiated baby in any delivery, but especially if the delivery is prolonged, obstructed or if the liquor is thick and green.
3. Record the exact time of birth. Start counting time.
4. Place baby on a clean cloth on a flat surface.
5. Clean the nose and mouth with a clean gauze.
6. Clean and dry the skin of the baby with a soft cloth.
7. At 60 seconds (1996 to 1999), or at 30 seconds (from 1999) examine the cry and respiration
   If both are present and vigorous — normal.
   If any one of the following is present: no cry or no breathing or weak breathing/gasping; diagnose as asphyxia and perform further steps.
8. Clean mouth, throat and nose with mucus extractor.
9. If baby did not yet cry/breathe, clamp and cut the umbilical cord.
10. Place the baby on a flat surface, with a folded cloth under shoulders to extend the neck.
11. Open the mouth. Place the mask on mouth and nose.
12. Ventilate lungs (tube and mask (1996 to 1999) or bag and mask (1999 to 2003)) 30 to 40 times a minute. Observe the chest expansion.
13. Stop and observe for spontaneous breathing once every minute.
14. Record the breathing at 5 minutes.
15. Stop ventilating either when the baby starts breathing spontaneously or if no breathing even at 15 minutes — declare as stillbirth.
16. Record all events, findings and outcome.
17. If a neonate was asphyxiated and ventilated at birth, consider it as a ''high-risk'' neonate and visit more frequently.

Period	Worker	Intervention / Equipment	Indicators available
1988 - 95	**TBA**[*]	Cleaning of mouth **Mouth to mouth** resuscitation	1. ASMR[$] ,based on verbal autopsy (1988- 99)
1995 - 96	**TBA** + VHW[#]	TBA as above VHW only observed and recorded	1. As above 2. Incidence of asphyxia 3. % Case fatality 4. ASMR[$], based Primary cause of death
1996 - 99	**VHW** + TBA	An algorithm of how to manage birth asphyxia Cleaning face, drying skin with a cloth. Resuscitation started at 1 minute with **Tube and mask**	1 , 2 , 3 , 4 5. Fresh still birth rate
1999 - 03	**VHW** + TBA	Same algorithm Cleaning face, drying skin with a cloth. Resuscitation started at 30 seconds with **Bag and mask.**	2, 3, 4, 5.

* : Traditional birth attendant.
# : Village health worker.
$: Asphyxia specific mortality rate.
Note : The underline indicates the worker who managed asphyxia at birth, and the method/instrument used for resuscitation.

Figure 1. Management of birth asphyxia in different periods during 1988 to 2003, in Gadchiroli.

Equipment

The VHWs used room air for ventilation. The mucus extractor was of plastic, with a mucus trap and was disposable (Romson, India).

The tube and mask were made of silicon rubber, and had a safety valve to prevent excessive pressure (Phoenix, Chennai, India). Masks of two sizes were given to the VHW to be used according to the size of the baby. The price of the tube and mask was $10. Bag and mask (Phoenix, Chennai, India), of a size 280 ml, and with a price of $20 also had a safety valve. No drugs were used in resuscitation.

We introduced health education from 1997, provided by the VHW, to individual pregnant woman by using a flip chart and by way of the group health education session. The messages included need for antenatal check up and birth preparedness.

To encourage a VHW to be present during home delivery, she was paid by SEARCH an incentive ($1.00), if the TBA and the family confirmed her presence at the birth to the supervisors. VHWs could remain present in some of the hospital deliveries as well. From 2000, the government encouraged institutional delivery, and introduced a financial incentive of $15.00 if the woman delivered in a government institution (health subcentre manned by a nurse-midwife or in a hospital). The incentive money was paid to the family.

Private rural medical practitioners (usually unqualified) or nurses were often called by a family to ''treat'' the woman in labour. The ''treatment'' most often involved administering intravenous saline and oxytocics. Even in such cases, the actual delivery was conducted by a TBA and the neonate managed by a VHW.

Analysis

All data, vital statistics, mother–newborn records and treatment records, verbal autopsy reports were computer entered. They were analyzed by SPSS-PC + (Version 3) and Epi info (Version 5). The χ^2-test with Yate's correction was used for estimating the significance.

Consent and Ethical Clearance

Community consent was obtained from all 39 intervention villages in the form of a signed resolution. Every family was free to refuse the visit and the care provided by a VHW. An external advisory committee gave ethical clearance and monitored the trial.[14]

RESULTS

The intervention area included 39 villages in Gadchiroli, with a total population of 38,998 in 1994.

The number of deliveries, place of delivery and type of attendant at delivery in the intervention villages during 1995 to 1996 (without active intervention) and during 1996 to 2003 (with active

interventions of home-based neonatal care) are presented in Table 2. Nearly 89 to 95% of deliveries were at home, almost all of them conducted by TBAs. The proportion of institutional deliveries increased from 5 to 10% during intervention period because of the incentive money offered by the government for institutional delivery. This increase occurred from the year 2000, and it may explain the proportion of caesarian deliveries increasing from 0.5 to 2%. The presence of a VHW at delivery also increased from 78 to 84%. The doctors called during home delivery were invariably unqualified private doctors who quickened the delivery by giving oxytocics.

The estimated incidence and mortality due to asphyxia in the intervention area during the year 1995 to 1996 are presented in Table 1. The incidence of mild asphyxia was relatively high, but it did not show association with risk of death. Severe asphyxia showed high CF (38%) and high association with the risk of death (RR 8.0). Out of the NMR of 52 per 1000 live births, 10.5, that is, approximately 20% was ascribed to asphyxia by the neonatologist. This became the preintervention baseline.

The effect of home-based neonatal care on the incidence of birth asphyxia during the 7 years of intervention is shown in Table 3. The incidence of mild asphyxia declined progressively and markedly but that of severe asphyxia did not change.

The effect of interventions on mortality indicators is presented in Table 4. Since mild asphyxia had no association with the risk of death, it was omitted. The table shows that the CF declined by nearly 50% ($p<0.07$) and the ASMR by 65% ($p<0.02$).

The comparison of the CF, ASMR and fresh SBR during the three types of resuscitation methods employed during different years is presented in Table 5. The ASMR declined significantly and equally with the tube and mask and the bag and mask. The CF and fresh SBR were substantially (though not significantly) less with the bag and mask as compared to

Table 2 Type of Delivery and the Attendance at Birth in the Intervention Area

	1995–1996		1996–2003	
	Number	%	Number	%
Total deliveries	782	—	5651	—
Live births	763	—	5510	—
Type of delivery (%)				
Institutional*	43	5.5	586	10.4
By caesarian section	4	0.5	71†	2.1†
Home	739	94.5	5033	89.1
Not recorded	0	0.0	32	0.6
Home deliveries conducted by TBA	680	92.0	4874	96.8
VHW present in home deliveries	574	77.7	4218	83.8
Doctor called at the time of home delivery	181	24.5	1269	25.2
Doctor gave injection at the time of home delivery (oxytocics)	171	23.1	1068	21.2

*Hospital, but during 1996 to 2003 also included health subcentres.
†Out of 3335 deliveries on which these data were available.
TBA = traditional birth attendant; VHW = village health worker.

Table 3 Effect of Home-Based Neonatal Care on the Incidence of Birth Asphyxia (Before–After Comparision in the Intervention Area)

	Incidence %				% Change 1995–1996 to 2000–2003	*p*
	Managed by TBA	Managed by VHW				
	1995–1996	1996–1998	1998–2000	2000–2003		
Mild asphyxia*	14.2	8.4	5.9	5.7	−59.9	<0.0001
Severe asphyxia†	4.6	2.4	3.7	4.9	+6.5	NS

TBA = traditional birth attendant; VHW = village health worker.
*At 1 minute after birth, no cry, or the breath was absent or slow, weak or gasping. From the year 1998, the observation was made at 30 seconds, instead of at 1 minute.
†At 5 minutes after birth, the breath was absent or slow, weak or gasping.

Table 4 Effect of Asphyxia Management by Different Workers on Case Fatality and Mortality Rate due to Asphyxia (Before–After Comparision in the Intervention Area)

	TBA 1995–1996	VHW 1996–2003	% Change	*P*
Severe asphyxia* % C.F. (deaths/neonates)	38.5 (10/26)	20.2 (34/168)	−47.5	<0.07
Asphyxia specific mortality rate† (deaths/neonates)	10.5 (8/763)	3.6 (20/5510)	−65.4	<0.02

TBA = traditional birth attendant; VHW = village health worker; C.F. = case fatality.
*At 5 minutes after birth, the breath was absent or slow, weak or gasping.
†Based on the primary cause of death assigned by neonatologist.

Table 5 Before–After Comparision of Three Methods of Resuscitation in the Intervention Area

	TBA$ Mouth-to-mouth 1995–1996 **1**	VHW£ Tube and mask 1996–1999 **2**	VHW£ Bag and mask 1999–2003 **3**	% Change **1** vs **2**	**1** vs **3**	**2** vs **3**
Case fatality in severe asphyxia (%)	38.5	28.3	17.2	−26.5	−55.3*	−39.2
Asphyxia-specific mortality rate†/1000 live births	10.5	3.5	3.7	−66.7*	−64.8*	+5.7
Fresh SBR‡/1000 births	NR	18.4	12.4	—	—	−32.6[a]
Asphyxia mortality + freash still births/1000 births	—	21.9	16.0	—	—	−26.9

$TBA = traditional birth attendent;
£VHW = village health worker.
*$p<0.05$.
†Primary cause of death, assigned by neonatologist.
‡Still birth rate.
NR = not recorded.
[a] = $p<0.09$

the tube and mask. The CF difference between mouth-to-mouth resuscitation and the tube and mask was 26.5 (not significant), while with bag and mask it was 55.3% and significant. The fresh SBR was less with bag and mask as compared to tube and mask by 32.6%, and the difference was near significant. Thus out of the three mortality indicators, the tube and mask effectively reduced one while the bag and mask reduced all three.

This was an uncontrolled, before–after comparison between 1995 to 1996 and 1996 to 2003. Moreover, the effect of training the TBAs in mouth-to-mouth resuscitation could not be assessed in this comparison because they were trained earlier. However, it was assessed by comparing the ASMR based on the cause of death assigned by verbal autopsy — in both the intervention and the control area (Table 6). The cause assignment included multiple causes, that is, more than one cause was assigned to death, if more than one morbidity was present. Hence the ASMR are higher than in earlier tables when only a single primary cause was used. The comparison with the control area shows the effect of training TBAs in mouth-to-mouth resuscitation (11.7% reduction) and of VHWs using tube and mask (41.8% reduction) in the intervention area. The reduction is insignificant with mouth-to-mouth but highly significant with tube and mask. The verbal autopsy was stopped in 1999, so we cannot compare by this method the effect of bag and mask.

To assess the risk factors associated with the residual problem of asphyxia in the intervention phase, odds ratios (ORs) of severe asphyxia and fresh stillbirth were estimated for some of the risk factors on which we had collected data. These are presented in Table 7. The OR for these two considered together (A + B in Table 7) was high for preterm birth (3.8), twin delivery (3.5), low birth weight (1.8) and bad obstetrical history (1.5). It was also high (3.0) for injection (mostly oxytocics) given by private doctor during home delivery.

Discussions with VHWs revealed that they invariably preferred bag and mask because of the following difficulties with the tube and mask: (a) it was difficult to resuscitate for up to 15 minutes using tube and mask during which the worker is required to blow 30 to 40 times/minute. (b) They needed to continuously bend forward for 15 minutes, which was uncomfortable. (c) They could not be sure whether the blowing pressure was correct, especially as the fatigue set in.

Table 6 Effect on Birth Asphyxia as a Cause of Death Assigned by Verbal Autopsy* (1993–1999)

Year	Interventions	Intervention area			Control area			
		Live births	Asphyxia deaths	Asphyxia SMR†	Live births	Asphyxia deaths	Asphyxia SMR†	% Difference (control–intervention)
1993–1995	TBA mouth-to-mouth	1999	56	28.0	2271	72	31.7	−11.7
1995–1996	TBA+VHW presence	1016	25	24.6	1074	40	37.2	−33.9
1996–1997	VHW Tube and mask	804	15	18.7	940	22	23.4	−20.1
1997–1998	VHW Tube and mask	979	11	11.2	1108	39	35.2	−68.2
1998–1999	VHW Tube and mask	729	11	15.1	910	28	30.8	−51.0
1996–99	Three intervention years	2512	37	14.7	2958	89	30.1	−51.2**

Effect of TBA training in mouth-to-mouth resuscitation = (31.7−28.0) = 3.7 (11.7%)
Effect of VHW training+tube and mask = (28.0−14.7)−(31.7−30.1) = 11.7 (41.8%**)

*More than one cause is assigned to many deaths, and death counted in each cause. Hence, the rates are higher.
†Asphyxia specific mortality rate/1000 live births, based on verbal autopsy.
TBA = traditional birth attendant; VHW = village health worker.
**$p<0.001$.

Table 7 Risk Factors Associated with the Remaining Problems of Asphyxia (1996–2003)

Risk factor	Severe asphyxia (A) OR* (95% CI)	Fresh still births (B) OR* (95% CI)	For A+B OR* (95% CI)
Preterm birth (<37 weeks)	2.6 (1.8–4.0)	6.4 (4.0–10.2)	3.8 (2.8–5.1)
Low birth weight (< 2500 g)	1.8 (1.3–2.5)	—	1.8 (1.3–2.5)
Prolonged labour (>24 hours)	1.1 (0.4–2.7)	0.8 (0.2–2.5)	1.0 (0.5–2.0)
PROM (>24 hours)	1.6 (0.4–5.6)	0.4 (0.02–2.9)	0.9 (0.3–2.8)
Twins	2.5 (0.8–7.4)	4.5 (1.3–13.3)	3.5 (1.5–7.9)
Bad obstetrical history (stillbirth/neonatal death)	1.2 (0.8–1.9)	2.0 (1.2–3.5)	1.5 (1.1–2.1)
Injection given by private doctor (oxytocics)	2.6 (1.9–3.6)	3.7 (2.4–5.8)	3.0 (2.3–3.9)

*: Odds ratio.

DISCUSSION

In this study, the home-based neonatal care interventions were introduced in rural Gadchiroli, where >90% of deliveries occur at home. The interventions included training a literate village woman, the VHW, to attend the delivery along with the TBA, and to take care of the neonate at birth including resuscitating if required. The interventions by the trained VHW reduced the asphyxia related mortality, the CF by nearly 50% and the ASMR by 65%, in comparison to management by a TBA alone. The incidence of mild asphyxia also reduced by 60%, but its importance cannot be judged because mild asphyxia was not associated with risk of death. The incidence of severe asphyxia did not decrease. This was understandable in view of the fact that the trial did not include any major obstetrical interventions, and the emphasis, almost entirely, was on immediate diagnosis and management of asphyxia. This could also be because some of the prevented fresh stillbirth may manifest as severe asphyxia.

The trial was not designed to compare different methods of resuscitation. But a comparison over different time periods suggests that for such home-based resuscitation, the bag and mask was more effective and acceptable to the care provider. Tube and mask was equally effective in reducing the ASMR, but the bag and mask was more effective in reducing the CF and fresh SBR, and it was easier for the VHWs to use. Mouth-to-mouth resuscitation by TBAs was the least effective. To further reduce the incidence and mortality due to asphyxia, better obstetrical care in the indicated deliveries and preventing the unnecessary use of oxytocics by unqualified doctors during home deliveries may be useful.

Based on this evaluation, we conclude that home-based interventions provided by a trained VHW present at birth, in addition to a TBA, were effective in reducing deaths due to asphyxia. The bag and mask appears to be more effective equipment for resuscitation.

There are several limitations of this evaluation. The total effect of asphyxia manifests in the form of CF, fresh stillbirths, and neurodevelopmental consequences. We have complete data on deaths (CF and ASMR), data on fresh SBR only from 1996, no data on neurodevelopmental effects. Hence, the evaluation is mostly possible only on CF and ASMR.

This was not a controlled trial of asphyxia management, and hence most of the evaluations are made by before–after comparison. It would be ethically impossible to observe asphyxia at birth but not intervene in the control group. The opportunity of observing without intervention was available only in the year 1995 to 1996 in the intervention area before the VHWs were trained in management of birth asphyxia, which provided the unique data on observing the natural incidence and fatality due to asphyxia. Hence, results of subsequent interventions have to be compared with the estimates in 1995 to 1996. As many other factors such as the maturation of the skills as the experience increases, or the introduction of other interventions, can also change the outcome indicators, the before–after comparisons are a less reliable evidence.

However, a controlled comparison is available of the ASMR based on the cause of death assigned by verbal autopsy for the baseline (1993 to 1995), observation (1995 to 1996) and intervention (1996 to 1999) periods (Table 6). Such comparison shows net 11.7% difference in the ASMR between the intervention and the control areas during 1993 to 1995. This difference is attributed to the earlier training of TBAs in mouth-to-mouth resuscitation in the intervention area. A 41.8% reduction in the ASMR due to training of VHWs and use of tube and mask was detected. The verbal autopsy was stopped in 1999, and hence we do not have results during 2000 to 2003 when the bag and mask was introduced.

The effect of mouth-to-mouth resuscitation by TBAs assessed by comparing the ASMR in the intervention and the control area in 1993 to 1995 (Table 6), as showing a difference of 11.7%, must be understood with two qualifications. The method of verbal autopsy has never been validated in neonates. The TBAs in the control area also had received training in the government program.

Community-based field studies of birth asphyxia suffer from imprecision because the diagnostic definition of asphyxia and the measurement are fraught with enormous difficulties.[20] The presence of a trained observer at the time of home delivery, clinical assessment of the neonate at 1 and 5 minutes, exact measurement of time in the presence of that emergency, the impossibility of subsequently counter checking the correctness of the recorded data, distinguishing asphyxia from other causes of failure to breathe at birth, the ethical impossibility of having a control group — all make such field studies very challenging. Hence, relatively imprecise measurements, estimates and evaluations are inherent limitations.

We have used a simple clinical definition by observing the neonate at 1 and 5 minutes. This definition has been validated in the hospital setting.[7] We changed the timing of the first observation from at 1 minute to 30 seconds starting in 1999. This change, if at all, should result in increased incidence of mild birth asphyxia. Hence, the reduced incidence of asphyxia during the intervention years cannot be explained by the change in the definition. However, earlier initiation of resuscitation may improve the outcome such as the % CF in severe asphyxia observed with the bag and mask.

CF and ASMR are based on deaths — a definite, verifiable event. This study shows a large and significant decrease in these two rates. The reduction in mortality may be caused by resuscitation at birth and by the subsequent supportive care of such neonates as high-risk babies (Box 1).

Can the observed effect in reduction in mortality be explained by some other changes? A small increase in the proportion of institutional deliveries and caesarian section deliveries occurred during the intervention period (Table 2). This was entirely after 1999 (yearwise data not presented), due to an incentive scheme introduced by the government in 2000 to unselectively encourage institutional deliveries. But that does not explain the reductions in the CF and ASMR (Table 4), which were entirely based on the home deliveries observed by VHWs or the reduction in ASMR observed during 1996 to 1999 (Tables 5 and 6). Moreover, the increase in hospital deliveries is very marginal. Hence, the observed reduction in asphyxia-related mortality is attributable to the home-based interventions.

There are few studies with which the results can be compared. A meta-analysis of the evaluations of training of TBAs has estimated the net reduction to be 8% in the perinatal mortality rate and 11% in the ASMR.[21] Our estimated reduction in the ASMR due to training of TBAs is comparable, 11.7% (Table 6). We cannot use the perinatal mortality rate to evaluate the effect of the interventions against asphyxia because our intervention package of home-based neonatal care included many other interventions to affect the neonatal mortality during days 1 to 7 that contributes to the perinatal mortality rate.

In a field trial of training of TBAs in rural North India, the effect of advanced training, including equipping with bag and mask, was compared with that of mouth-to-mouth resuscitation. The CF was less by 20% in the group with bag and mask, and the ASMR in the two groups was 6 per 1000 and 19 per 1000.[22,23] Our results on ASMR are of comparable magnitude, but on CF we found much more reduction: by 55%. In our experience, literate VHWs can observe and record better, as compared to the illiterate TBAs who cannot count or record. VHWs can be better trained to follow an algorithm (Box 1). Moreover, TBA + VHW makes for a better team to manage mother and neonate at that critical moment of birth.

The main limiting factors for implementation are the cost of training and equipment, and rarity of use. Tube and mask ($10.00) was cheaper than bag and mask ($20.00). An average TBA in our area conducts 5 to 20 deliveries, and a VHW attends 20 to 25 deliveries per year. With the incidence of mild asphyxia less than 6% (Table 3) the need for using resuscitation equipment may arise once or twice in a year. Hence, the utilization rate is relatively low.

In the subsequent article,[24] we have estimated that the home-based interventions in the Gadchiroli trial averted 31 asphyxia related neonatal deaths in 39 villages during 1996 to 2003. (If bag and mask were used from the beginning of intervention, probably more deaths would have been averted.) In addition, bag and mask averted six fresh stillbirths per 1000 births (Table 5), therefore, would have averted additional 30 stillbirths during 1996 to 2003. Assuming one bag and mask per village (no need to replace the equipment has been experienced so far) the cost of the bag and mask was estimated to be $13 per averted death (fresh stillbirths + asphyxia related neonatal deaths). The cost of training and remuneration to VHWs as well as the outcome such as averting neurological consequences are not taken into calculation.

However, a more difficult but crucial prerequisite is to ensure the presence of a trained worker at the time of home-delivery. In spite of creating a full-time paid cadre, called an 'auxiliary nurse-midwife' one per 5000 population, in the entire country nearly 15 years ago, the national program in India has reported presence of this worker during only 15% of home deliveries.[25] A VHW being a resident woman from the same village is more likely to attend home deliveries. VHWs attended 84% home deliveries in Gadchiroli trial (Table 2). Choice of equipment will be effective only if the worker is present at birth.

Nearly 60% reduction in the incidence of mild asphyxia is an effect of the presence of two birth attendants, TBA + VHW, instead of one, and the resultant immediate drying, tactile stimulation and cleaning of throat. This reduced the need for resuscitation with tube or with bag to nearly to 6% (incidence of mild asphyxia) in the last 5 years of interventions. However, it is unlikely to have any effect on mortality because, to begin with, the mild asphyxia was not associated with an increased risk of death (Table 1).

In the postintervention scenario, the risk factors associated with the severe asphyxia or fresh stillbirth (Table 7) were all presumably obstetrics related. The unnecessary practice of administering oxytocics was clearly associated with three-fold risk of these events. As the prolonged labour did not show increased risk of birth asphyxia in this cohort, it did not act as a confounder causing a spurious association between the use of oxytocics and birth asphyxia. This harmful practice needs immediate attention.

CONCLUSIONS

This study demonstrates a significant effect of home-based neonatal care on mortality due to asphyxia. To deliver such an intervention, it is necessary to form a team of a semiskilled VHW with the TBA, so that each home delivery is attended not by a TBA alone but by two birth attendants. For resuscitating an asphyxiated baby in such setting, bag and mask appears to be more effective than tube and mask or mouth-to-mouth breathing, and more convenient to use. The estimated cost of bag and mask was $13 per averted death.

References

1. World Health Organization. The World Health Report, 1998: Life in 21st Century — A Vision for All. WHO: Geneva; 1998.
2. State of the World's Newborns. Save the Children. Washington, DC; 2001.
3. Wiggleworth JS. Monitoring perinatal mortality: a patho-physiological approach. Lancet 1980;2:684–6.
4. Keeling JW, MacGillivry I, Golding J, Wiggleworth JS, Berry J, Dunn PM. Classification of perinatal death. Arch Dis Child 1989;64: 1345–51.
5. Ellis M, Dharma M. Progress in Perinatal Asphyxia. Semin Neonatol 1999;4:183–91.
6. Singh M, Paul VK, Bhakoo ON. Neonatal Nomenclature and Data Collection. New Delhi: National Neonatology Forum; 1989. p. 63–74.
7. Singh M. Diagnosis and management of perinatal asphyxia. Indian Pediatr 1994;31:1169–74.
8. Kumar R. Birth asphyxia in a rural community in North India. J Trop Pediatr 1995;41:5–7.
9. Indian Council of Medical Research. A national collaborative study of identification of high risk families, mothers and outcome of their offsprings with particular reference to the problem of maternal nutrition, low birth weight, perinatal and infant morbidity and mortality in rural and urban slum communities. An ICMR Task Force Study. New Delhi: Indian Council of Medical Research; 1990.
10. Bang AT, Bang RA, Baitule S, Deshmukh M, Reddy MH. Burden of morbidities and the unmet need for health care in rural neonates — a prospective observational study in Gadchiroli, India. Indian Pediatr 2001;38:952–65.
11. Bang AT, Reddy HM, Baitule SB, et al. Incidence of morbidities in a cohort of neonates in rural Gadchiroli, India: Seasonal & temporal variation & a hypothesis about prevention. J Perinatol 2005;25:S18–28.
12. Bang AT, Paul VK, Reddy HM, et al. Why do neonates die in rural Gadchiroli, India? (Part I). Primary causes of death assigned by neonatologist based on prospectively observed records. J Perinatol 2005;25:S29–34.
13. Bang AT, Reddy HM, Bang RA, Deshmukh M. Why do neonates die in rural Gadchiroli, India? (Part II). Estimating population attributable risks and contribution of multiple morbidities for identifying a strategy to prevent deaths. J Perinatol 2005;25:S35–43.
14. Bang AT, Bang RA, Baitule S, Reddy MH, Deshmukh M. Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. Lancet 1999;354:1955–61.

15. Bang AT, Bang RA. Background of the field trial of home-based neonatal care in Gadchiroli, India. J Perinatol 2005;25:S3–10.
16. Bang AT, Bang RA, Reddy HM, et al. Methods and the baseline situation in the field trial of home-based neonatal care in Gadchiroli, India. J Perinatol 2005;25:S11–7.
17. Bang AT, Bang RA, Tale O, et al. Reduction in pneumonia mortality and total childhood mortality by means of community-based intervention trial in Gadchiroli, India. Lancet 1990;336:201–6.
18. Bang AT, Bang RA and the SEARCH team. Diagnosis of causes of childhood deaths in developing countries by verbal autopsy: suggested criteria. Bull World Health Organ 1992;70(4):499–507.
19. Bang RA, Bang AT and SEARCH Team. Commentary on a community based approach to reproductive health care. Int J Gynecol Obstet 1989;3: 125–9.
20. Ellis Matthew. Birth asphyxia in developing countries. In: Costello A, Manandhar D, editors. Improving Newborn Infant Health in Developing Countries. London: Imperial College Press; 2000. p. 233–72.
21. Sibley L, Sipe TA. What can a meta-analysis tell us about traditional birth attendant training and pregnancy outcomes? Midwifery 2004;20(1):51–60.
22. Kumar R. Training traditional birth attendants for resuscitation of newborns. Trop Doctor 1995;25:29–30.
23. Kumar R. Effect of training on the resuscitation practices of traditional birth attendants. Trans Roy Soc Trop Med Hyg 1994;88:159–60.
24. Bang AT, Reddy HM, Deshmukh MD, et al. Neonatal and infant mortality in the ten years (1993 to 2003) of the Gadchiroli field trial: Effect of home-based neonatal care. J Perinatol 1995;25:S92–107.
25. International Institute of Population Sciences. The National Family Health Survey 1998–99: The Key Findings. Mumbai: IIPS; 1999.